

REMARKS

This responds to the Office Action dated 26 June 2006.

Claims 3, 103, 110, 112, 114, 124-127, 133, 137, 139, 140, 143, 147-150, and 152 are amended, no claims are canceled, and claims 153-170 are added; as a result, claims 1-5 and 103-170 are now pending in this application. The amendments to the claims are fully supported by the specification as originally filed. No new matter is introduced. Applicant respectfully requests reconsideration of the above-identified application in view of the amendments above and the remarks that follow.

Claims 3, 103, and 133 are amended into independent form. Claims 110, 112, 114, 124-127, 137, 139, 140, 143, 147-150, and 152 are amended to clarify these claims. In addition, support for amendments to claims 110, 112, 114, 137, 139, and 140 may be found in the specification, for example, at page 37, lines 20 - 29. In addition, support for amendments to claims 124-127, 143, 147-150, and 152 may be found in the specification, for example, from page 34, line 22 - page 35, line 2. Support for claims 153-170 may be found in the specification, for example, from page 41, line 29 - page 44, line 18, and Figures 17A and 17B.

Objections to the Drawings

The drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) for including a reference character in Figure 10A not mentioned in the description. Applicant amends the specification to include the reference character as used in original drawing of Figure 10A. Applicant submits that the amendment to the specification overcomes this objection to the drawings. No new matter is introduced.

The drawings were also objected to on the grounds that reference characters and figure numbers were hand-drawn, and some text in Figures 5, 10A, and 10B was of insufficient quality for reproduction. Corrected drawings are supplied herewith. No new matter is introduced.

Applicant respectfully requests withdrawal of these objections to the drawings.

In the Specification

Applicant amends the paragraph in the specification, beginning at page 31, line 5, to include the reference character "1060" and material referenced by the reference character "1060"

as used in original drawing of Figure 10A. No new matter is introduced.

Objections to the Specification

The specification was objected to due to informalities. The specification is amended to correct the informalities as suggested by the Examiner. No new matter is introduced.

Applicant respectfully requests withdrawal of these objections to the specification.

Objections to the Claims

Claims 111, 113, 114, 124-131, 138 and 143-152 were objected to for informalities. Claim 110 is amended to include the terms “acceleration pulse waveform” and “acceleration step waveform.” Claim 112 is amended in view of the amendments to claim 110. In light of the amendments to claim 110, Applicant submits that the objections to claims 111, 113, and 114 have been addressed. Claim 137 is amended to include the terms “acceleration pulse waveform” and “acceleration step waveform.” Claim 139 is amended in view of the amendments to claim 137. In light of the amendments to claim 137, Applicant submits that the objections to claim 138 have been addressed. Claims 124, 138, 143, and 147 are amended in line with the comments by the Examiner. Claims 125-131, claims 144-146, and claims 148-152 depend on claims 124, 143, and 147, respectively. No new matter is introduced.

Applicant respectfully requests withdrawal of these objections to claims 111, 113, 114, 124-131, 138 and 143-152, and reconsideration and allowance of these claims.

§ 102 Rejection of the Claims

Claims 1 and 2 were rejected under 35 U.S.C. § 102(e) for anticipation by Watt et al. (U.S. Patent Publication No. 2002/0151818). Applicant traverses these grounds of rejection of these claims.

Applicant reserves the right to swear behind Watt et. al (hereafter Watt) at a later date. Applicant cannot find in Watt a disclosure, a teaching, or a suggestion of a method that includes turning off vestibular responses in one ear of a subject and evaluating vestibular response in the other ear of the subject as recited in claim 1. In the Office Action with respect to Watt, it is stated that “[a]n applied stimulus (paragraph 9) has a component directed to essentially

completely inhibit activity in a semicircular canal of one ear.” Paragraph 9 of Watt recites:

[0009] Australian researchers Ian Curthoys and Michael Halmagyi (Halmagyi, G. M., Curthoys, I. S., Cremer, P. D., Henderson, C. J., Todd, M. J., Staples, M. J. and D'Cruz, D. M. The human horizontal vestibulo-ocular reflex in response to high-acceleration stimulation before and after unilateral vestibular neurectomy. Exp. Brain Res. 81: 479-490,1990.) have demonstrated a far simpler technique that measures eye movements during the first 100 msec of an unpredictable, passive horizontal head rotation (peak head displacement 20.degree., peak head velocity 200-300.degree./sec, peak head acceleration 2000-4000.degree./sec.sup.2). When eye velocity is plotted as a function of head velocity in patients with an unilateral loss of vestibular function, eye responses during rotations toward the intact side are found to be close to normal but the responses are found to be markedly decreased when the rotation is toward the lesioned side. Most significantly, this deficit appears to be permanent, implying that it cannot be hidden by compensatory mechanisms.

Applicant notes that plotting eye velocity as a function of head velocity in patients already having a unilateral loss of vestibular function does not disclose, teach, or suggest affirmatively turning off vestibular functions in one ear of a subject.

In the Office Action, it is stated “that it is inherent that the stimulus will completely inhibit activity in a semicircular canal of the one ear because it is of a high magnitude.” Applicant respectively disagrees with the application of the language “of a high magnitude” as proffered in the Office Action. Further, Applicant traverses the use of inherency as applied in the Office Action, since it has not been established that Watt uses a magnitude of rotation sufficient to turn off vestibular responses in one ear. Applicant respectfully submits that a *prima facie* case of inherency has not been established in the Office Action. MPEP § 2112 recites that “In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art,” citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Applicant notes that there is some threshold magnitude of rotation at which and above which vestibular responses will turn off. However, Applicant cannot find in Watt a disclosure, a teaching, or a suggestion that Watt applies a rotation of sufficiently high magnitude to turn off vestibular responses. Rather, it appears that Watt applies rotation of high magnitude to provide measurable vestibular responses, where the head and body of the patient remain fixed rather than rotating the head

relative to the body.

Factors determining whether a rotational stimulus results in a complete inhibition of semicircular canal activity include the magnitude of the acceleration and the duration of the acceleration. A high magnitude acceleration in itself would not necessarily result in an inhibition of semicircular canal activity if the duration of the acceleration was too short. As recited in claim 1, an inventive method of the instant application includes turning off vestibular responses in one ear of the subject and evaluating vestibular response in the other ear of the subject. A further method includes substantially inhibiting activity in the semicircular canal in one ear while the other ear is tested. A method of the instant application includes using stimuli designed so that one component of the stimuli (the bias component) would substantially inhibit activity semicircular canal in one ear while the other ear is tested (using the probe component of the stimulus).

Halmagyi et al., referenced in Watt as indicated in the above quote, found that the stimulus they used was able to identify a semicircular canal asymmetry by comparing responses from rightward and leftward head rotations. The Watt invention relates to a method to provide a stimulus similar in magnitude to the stimulus described in the Halmagyi et al. reference, where the Watt invention has some other advantages in that the whole body is moved rather than just the head. The stimuli used by Halmagyi and Watt provides an impulsive stimulus large enough to reveal a difference between eye movement responses from rightward and leftward head rotations in patients who have a unilateral reduction in vestibular function (or more specifically in semicircular canal function). Watt reports (paragraph [0035]) that the magnitude of the stimulus he was able to obtain in his invention prototype was "slightly lower" than the stimulus used by Halmagyi. Watt reports only the peak velocity (175°/s) and peak angular displacement (7° achieved in 100 ms), but does not report the peak acceleration. The magnitude of the peak acceleration and the time course of the acceleration would be needed to determine the extent to which activity in the semicircular canals was completely inhibited. Both Watt and Halmagyi, as referenced in Watt, were able to identify evoked eye movement asymmetries in patients with a unilateral vestibular loss using their stimuli of different magnitudes. Watt's method apparently uses stimulus sufficiently large so as to evoke asymmetric eye movements. It is not clear from the Watt results and from the comparison with Halmagyi that it is necessary to essentially

completely inhibit activity in an ear using the Watt method, but only that it is necessary for the stimulus to be “large” with “large” not being clearly defined.

Both the Halmagyi study and the Watt patent use a single rapid movement from one position to another. This is essentially a “unitary” process. Claim 1 recites a binary process, that is, turning off vestibular response in one ear and evaluating the vestibular response in the other ear, which may be performed essentially simultaneously. In contrast, the Watt method relates to the unitary process of providing an impulsive stimulus that is large enough to evoke asymmetric responses.

Applicant submits that Watt does not teach each and every claim element of claim 1 and/or that Watt does not teach the identical invention in as complete detail as is contained in claim 1. Thus, Applicant submits that Watt does not anticipate claim 1 and that claim 1 is patentable over Watt. Claim 2 is dependent on claim 1. Therefore, claim 2 is patentable over Watt for at least the reasons stated above with respect to claim 1.

Applicant respectfully requests withdrawal of these rejections of claims 1 and 2, and reconsideration and allowance of these claims.

§103 Rejection of the Claims

Claim 132 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Watt et al. (U.S. Patent Publication No. 2002/0151818) in view of Ledley et al. (U.S. Patent No. 4,474,186). Applicant traverses these grounds of rejection of this claim.

For at least reasons similar to those discussed above with respect to claim 1, Applicant submits that claim 132 is patentable over Watt. Applicant submits that combining Ledley et al. with Watt, as proffered in the Office Action, does not cure the deficiencies of citing Watt with respect to claim 132. Thus, claim 132 is patentable over Watt et al. in view of Ledley et al.

Applicant respectfully requests withdrawal of these rejections of claim 132, and reconsideration and allowance of this claim.

Allowable Subject Matter

Claims 3-5, 103-131, and 133-152 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of

the limitations of the base claim and any intervening claims.

In the Office Action assertions regarding features of some of the claims are made. Applicant respectfully submits that the relevant claims may be allowable for one or more reasons in addition to and/or in alternative to those reasons identified in the Office Action. Applicant reserves the right to further address one or more aspects of these statements in the Office Action as may later be necessary or desirable.

Claims 3, 103, and 133 are amended into independent form including all of the limitations of the base claim and any intervening claims. Claims 4 and 5 depend on claim 3, claims 104-131 depend on claim 103, and claims 134-152 depend on claim 133.

Applicant respectfully requests withdrawal of these objections of claims 3-5, 103-131, and 133-152, and reconsideration and allowance of these claims.

New Claims

New claims 153-161 are dependent on claim 103 and new claims 162-170 are dependent on claim 133. Therefore, claims 153-170 are consonant with the restriction requirement of 16 March 2006. Applicant respectfully requests consideration and allowance of claims 153-170.

Assertion of Pertinence

Applicant has not responded to the assertion of pertinence stated for the patents cited, but not relied upon, by the Office Action since these patents are not relied upon as part of the rejections in this Office Action. Applicant is expressly not conceding they have any pertinence and reserves the right to respond more fully should any of them form a part of some future rejection.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 371-2157 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

ROBERT J. PETERKA


By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2157

Date

18 September 2006

By


David R. Cochran
Reg. No. 46,632

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18 day of September 2006.

Name

John D. Gustafson - Weidall


Signature